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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,617	02/12/2004	Patrice Andre	111737.01	3955

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,617	ANDRE ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *24-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed August 12, 2004 is acknowledged and entered. Claims 24-46 are pending and subject to the following restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 24-37, drawn to a method of cultivating Hepatitis C, classified in class 435, subclass 5.

II. Claims 24-37, drawn to a method of cultivating Hepatitis G, classified in class 435, subclass 5.

III. Claim 38, drawn to a method of obtaining antibodies to Hepatitis C, classified in class 435, subclass 7.1.

IV. Claim 38, drawn to a method of obtaining antibodies to Hepatitis G, classified in class 435, subclass 7.1.

V. Claims 39 and 40, drawn to antibodies to Hepatitis C, classified in class 424, subclass 161.1.

VI. Claims 39 and 40, drawn to antibodies to Hepatitis G, classified in class 424, subclass 161.1

VII. Claim 41, drawn to a method for screening antiviral molecules against Hepatitis C, classified in class 435, subclass, 4.

VIII. Claim 41, drawn to a method for screening antiviral molecules against Hepatitis G, classified in class 435, subclass, 4.

IX. Claims 42-43, drawn to a method for preparing Hepatitis C viral particles, classified in class 435, subclass 4.

X. Claims 42-43, drawn to a method for preparing Hepatitis G viral particles, classified in class 435, subclass 4.

XI. Claims 44-46, drawn to Hepatitis C particles, classified in class 424, subclass 228.1

XII. Claims 44-46, drawn to Hepatitis G particles, classified in class 424, subclass 225.1

3. The inventions are distinct, each from the other because of the following reasons:

a) Groups I, III, V, VII, IX and XI are drawn to methods or products related to HCV (Hepatitis C virus). Groups II, IV, VI, VIII, X and XII are drawn to methods or products related to HGV (Hepatitis G virus). These viruses are distinct because they have different structures, though related by some general Hepatitis structures and features. Their genomes are different, and antibodies that bind to HCV will not necessarily bind to HGV because their epitopes are not identical. The antibodies of Groups V and VI, elicited to HCV and HGV will differ with regard to their variable portions. The HCV and HGV particles of Groups XI and XII are not the same.

b) Groups (I, II), (III, IV), (VII, VIII) and (IX,X) are distinct methods. The methods are drawn to cultivating HCV and HGV, screening antivirals against HCV and HGV, eliciting antibodies to HCV and HGV, and preparing HCV and HGV viral particles. These methods are related by HCV and HGV, however, the outcomes of the methods are not the same. Cultivating HCV and preparing HCV particles are distinct methods, because the particles are not complete

viruses, thus requiring manipulation of the genome. A method of eliciting antibodies to HCV does not share method steps with a method of screening antiviral molecules.

c) Inventions (III, IV) and (V, VI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies can be made synthetically.

d) Inventions (IX, X) and (XI, XII) are related as process of making and product made. The particles can be made recombinantly.

e) Inventions (V, VI) and (XI, XII) are distinct products. Antibodies to Hepatitis C or Hepatitis G are structurally different from HCV or HGV particles. They do not share structure or function.

f) The methods of inventions (I-IV, VII and VIII) are not required to practice the methods of inventions IX and X. Cultivating virus, eliciting antibodies and screening antivirals is not required to preparing HCV or HGV particles. Further, eliciting antibodies, screening antivirals and preparing viral particles is not required to cultivate HCV or HGV. Further, eliciting antibodies, cultivating HCV or HGV, and preparing viral particles is not required to practice the method of screening antivirals. Therefore, the methods are distinct from each other.

Because these inventions are distinct for the reasons given above and the literature search required for one group is not co-extensive for any other group, and therefore a serious burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even

though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product

and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B Chen

Stacy B. Chen
March 7, 2005